

Jakub Blair

☎ (704) 555-6193 ✉ jakub.blair@example.com 💼 linkedin.com/example/jakubblair 📍 Charlotte, NC 28203

SUMMARY

Senior **engineering** and **capital projects** leader with 15 years of experience across regulated medical device and manufacturing environments, including more than 8 years in engineering, 7 years directing technical projects, and 5 years leading people. Guides capital equipment strategy, **capacity expansion**, new product introduction, equipment qualification, validation, and multi site project governance. Connects engineering, R&D, Quality, supply chain, procurement, facilities, finance, and legal partners through clear plans, risk reviews, budgets, cash flow forecasts, and executive reporting. Develops Project Leads through coaching, **performance reviews**, measurable goals, and succession planning. Builds inclusive, safety focused teams while resolving technical issues and improving production capability. Brings practical judgment, finance awareness, and regulated manufacturing experience that can support reliable capital delivery and long term operational value.

EXPERIENCE

Director, Capital Projects Engineering

January 2023 - Present

ClearSight Medical Systems

Charlotte, NC

Lead a multi site capital engineering portfolio for regulated ophthalmic manufacturing, directing Project Leads across capacity, modernization, equipment optimization, and new product programs. Own portfolio governance, capital planning, executive reporting, and technical risk decisions while developing engineering leaders and strengthening safety, inclusion, and regulatory discipline.

- Directed ophthalmic capacity programs across sites, improving scope visibility through PMO governance and portfolio reviews.
- Coordinated procurement, installation, **qualification**, and validation with Quality, **R&D**, finance, facilities, and legal partners.
- Managed **capital budgets**, cash flow forecasts, and executive reports, keeping investment decisions aligned with business priorities.
- Developed **Project Leads** through coaching, performance reviews, succession **planning**, and measurable capability goals.
- Established SOW controls, change management, and escalation practices, improving schedule and technical risk visibility.
- Sponsored **equipment optimization** initiatives that supported compliant production, technology adoption, and reliable plant performance.

Senior Engineering Manager

March 2019 - December 2022

Pinnacle Surgical Technologies

Durham, NC

Managed engineering teams delivering capital equipment and manufacturing technology programs for FDA regulated surgical products across two facilities. Connected technical planning, supplier execution, site readiness, qualification, financial control, and people development with senior site priorities and production needs.

- Managed capital equipment programs across two **facilities**, linking technical decisions with FDA regulated production needs.
- Directed vendor selection, **installation**, commissioning, qualification, and operational transfer for surgical product programs.
- Partnered with **finance** on capital forecasts and cash flow, giving senior leaders timely investment choices.
- Aligned product development, manufacturing, **Quality**, **procurement**, facilities, and suppliers during new product introductions.
- Identified high potential engineers through **performance reviews** and development planning, expanding future Project Lead capacity.
- Resolved equipment issues through risk assessment, technical reviews, and coordinated corrective actions with site partners.

Technical Project Manager

June 2015 - February 2019

Meridian Medical Manufacturing

Greenville, SC

Led technical projects for equipment upgrades, capacity additions, and process technology changes in regulated medical device manufacturing. Built practical controls for schedules, budgets, suppliers, qualification activities, risk plans, and production handoffs, helping engineering work move from concept into dependable operations.

- Led capacity additions and **equipment upgrades**, connecting engineering scope with production and **validation** milestones.
- Built schedules, budgets, risk plans, and reports that clarified dependencies across engineering, Quality, and facilities.
- Coordinated suppliers through requirements, design reviews, factory acceptance, **installation**, **qualification**, and handoff.
- Supported capital requests with cost estimates, technical rationale, timing, and expected manufacturing benefits.
- Applied PMO tools to track decisions, SOW commitments, dependencies, and corrective actions across projects.
- Converted production constraints into prioritized equipment improvements, helping teams focus resources on operational needs.

Manufacturing Engineer

July 2012 - May 2015

Blue Ridge Precision Health

Asheville, NC

Supported **manufacturing equipment** and process engineering for precision healthcare products in a regulated production environment. Worked with Quality, operations, vendors, and contractors on equipment improvements, validation documentation, investigations, cost estimates, and safe implementation across the production floor.

- Supported equipment improvements through requirements, vendor coordination, **installation** support, testing, and controlled documentation.
- Analyzed equipment performance and production constraints, identifying practical opportunities for dependable output.
- Prepared **validation** documents, change controls, investigations, and compliant process improvements with Quality and operations.

- Created technical reports, schedules, cost estimates, and status updates for engineering and manufacturing stakeholders.
- Promoted safe practices during equipment modifications, contractor activity, and production floor implementation.
- Tracked implementation issues through structured reviews, helping operations resolve constraints before production handoff.

Project Engineer

June 2011 - June 2012

Carolina Applied Engineering

Winston Salem, NC

Executed early career equipment and facility improvement assignments for manufacturing clients under senior engineering oversight. Prepared requirements, vendor comparisons, schedules, installation plans, issue logs, cost tracking, and turnover records while building a foundation in project controls and manufacturing engineering.

- Prepared technical requirements and vendor comparisons for small capital equipment assignments under senior oversight.
- Built schedules and **installation** plans that helped contractors and plant stakeholders coordinate delivery activities.
- Supported equipment delivery, installation, testing, and turnover through regular contractor and plant coordination.
- Maintained issue logs, cost tracking, and status reports that supported timely project decisions.
- Applied structured problem solving to equipment reliability constraints, documenting recommended actions for senior engineers.
- Promoted safe work practices during facility improvements, equipment changes, and production floor activities.

PROJECTS

Ophthalmic Capacity Portfolio Governance 📅 2026

A growing production portfolio needed a clearer view of investment choices. Established practical governance across capital scope, risk, reporting, SOW controls, and escalation, giving Project Leads and senior partners a shared basis for decisions.

Surgical Equipment Qualification Program 📅 2022

Equipment handoff became a cross functional test of planning and trust. Connected vendors, engineering, Quality, facilities, procurement, and operations through installation, commissioning, qualification, and transfer activities for regulated surgical products.

LEADERSHIP & AWARDS

- Selected to lead multi site capital engineering governance for regulated ophthalmic manufacturing programs.
- Recognized for developing Project Leads through coaching, performance reviews, succession planning, and technical mentoring.
- Entrusted with executive reporting, capital budgets, cash flow planning, and technical risk escalation across major programs.

EDUCATION

Master of Engineering Management

2018

Duke University GPA: 4.0

Durham, NC

Coursework: Capital planning, financial analysis, operations strategy, project management

Bachelor of Science in Mechanical Engineering

2011

North Carolina State University GPA: 4.0

Raleigh, NC

Coursework: Manufacturing systems, facilities engineering, quality systems, engineering design

CERTIFICATIONS

- Project Management Professional, PMP 📅 2026
- FDA Regulated Manufacturing Project Management 📅 2026

TECHNICAL SKILLS

- **Capital Project Delivery:** Capital planning, capacity expansion, cash flow planning
- **Equipment Lifecycle:** Procurement, installation, commissioning
- **Qualification and Validation:** Equipment qualification, process validation, operational qualification
- **Medical Device Regulation:** FDA compliance, health agency regulation, controlled documentation
- **Project Governance:** PMO governance, PMM, SOW controls
- **Project Controls:** Schedules, budgets, risk registers
- **Financial Management:** Capital budgets, expenditure forecasts, cash flow targets
- **Manufacturing Engineering:** Capacity additions, equipment upgrades, process technology
- **Quality Systems:** Change control, investigations, corrective action
- **New Product Introduction:** Product development, production transfer, site readiness
- **Stakeholder Management:** R&D, Quality, procurement, facilities
- **People Management:** Hiring, coaching, performance reviews

- **Reporting Tools:** Executive reviews, project reporting, status updates
- **Safety Practices:** Safety culture, contractor safety, production floor safety
- **Technical Problem Solving:** Risk assessment, technical reviews, equipment optimization

SKILLS

- | | | | |
|----------------------|---------------------------|-------------------------|-------------------------------------|
| • Program Management | • Inclusive Leadership | • Regulatory Compliance | • Organizational Project Management |
| • Project Management | • Developing Others | • Capital Budgeting | • Project Management Office |
| • Risk Management | • Performance Measurement | • Agile Decision Making | • Statement of Work |
| • Team Management | • Project Reporting | • Analytics Insights | |

PROFESSIONAL AFFILIATIONS

- Project Management Institute, professional member supporting disciplined project delivery and continuing development.
- Medical device engineering community participant focused on regulated manufacturing, equipment qualification, and operational improvement.

LANGUAGES

- English (Native)
- Spanish (Beginner)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST